4

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/046,278	01/16/2002	C. Jane Robinson	06478.1463	2377

22852 7590 07/27/2005

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER	
HANLEY, SUSAN MARIE	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 07/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/046,278	ROBINSON ET AL.	
	Examiner	Art Unit	
	Susan Hanley	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 April 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The amendment submitted on 4/29/05 has been entered.

Claims 8-19 are pending.

Response to Amendment

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

Claims 8-15 stand rejected under 35 U.S.C. 102(e) as anticipated by O'Reilly (US 2002/0076413) in light of **Webster's Dictionary** (1994).

Applicant traverses this rejection on that grounds that the cited prior art did not expressly or inherently teach every element of the claim because O'Reilly teaches away from the instant invention. Applicant states that O'Reilly shows that AT3 having proteolytic catalytic activity, which is referred to as S-AT3, has virtually no effect on tumor volume or capillary cell proliferation and does not combat angiogenesis and that the proteolytically inactive form, referred to as R-AT3, possesses anti-angiogenic activity. Applicant alleges that the "active AT3" claimed in the instant application refers to AT3 having proteolytic activity.

Responding to Applicant's argument that the interpretation of "active" in the instant rejection does not take into account the definition for active AT3 in the specification, it is noted in the MPEP that the claims should be given their broadest, reasonable interpretation. All reasonable definitions are considered unless the text of the specification makes it clear that a word had a special meaning.

MPEP 2105

> ("Where there are several common meanings for a claim term, the patent disclosure serves to point away from the improper meanings and toward the proper meanings."). If more than one extrinsic definition is consistent with the use of the words in the intrinsic record, the claim terms may be construed to encompass

all consistent meanings. Tex. Digital, 308 F.3d at 1203, 64 USPQ2d at 1819. See also< Rexnord Corp. v. Laitram Corp., 274 F.3d 1336, 1342, 60 USPQ2d 1851, 1854 (Fed. Cir. 2001)(explaining the court's analytical process for determining the meaning of disputed claim terms); Toro Co. v. White Consol. Indus., Inc., 199 F.3d 1295, 1299, 53 USPQ2d 1065, 1067 (Fed. Cir. 1999)("[W]ords in patent claims are given their ordinary meaning in the usage of the field of the invention, unless the text of the patent makes clear that a word was used with a special meaning.").

In the instant case, the specification does provide a definition but the definition is not exclusive such that all other meanings of "active AT3" are not applicable. Therefore, all proper meanings have been considered and the dictionary definition of "active" is reasonable. Claim 8 is drawn to treating disorders characterized by angiogenesis or arteriogenesis and the specification shows that AT3 has anti-angiogenic activity. Thus, the phrase "active AT3" is interpreted to mean that that the AT3 is capable of functioning as an anti-angiogenic agent. In light of this interpretation, O'Reilly anticipates the claims because he teaches isoforms of AT3, i.e. R-AT3, that have anti-angiogenic activity for treating the claimed diseases.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., that the "active AT3" have serine protease activity) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Claims 8-10, 13, 15 and 17-19 stand rejected under 35 U.S.C. 102(e) as anticipated by Romisch et al. (US 6,399,572) in light of **Webster's Dictionary** (1994).

Applicant argues that the Office's interpretation of "active" does not take into account the definition for "active antithrombin III" which is provided in the instant specification. Applicant further argues that the case for inhenercy has not been established because the Office merely asserts that Romisch's method anticipates the claims because it generally uses ATIII to treat sepsis, vasculitits and rheumatoid arthritis. Applicant asserts that Romisch points out that the anti-inflammatory properties of AT3 concentrate are distinct from its anti-thrombin and anti-clotting capability. Applicant asserts that

one of ordinary skill in the art would not conclude from Romisch's disclosure that the use of AT3 to reduce inflammation caused by lippolysacchraides would always result in inhibition of antiogenesis or artiogenesis. Applicant argues that the Office has not set forth a *prima facie* case of anticipation because it has not demonstrated how control of lippolysaccharaide-induced cytokines would necessarily inhibit angiogenesis or artiogenesis.

Responding to Applicant's argument that the interpretation of "active" in the instant rejection does not take into account the definition for active AT3 in the specification, it is noted in the MPEP that the claims should be given their broadest, reasonable interpretation. All reasonable definitions are considered unless the text of the specification makes it clear that a word had a special meaning, see MPEP 2105 *supra.* In the instant case, the specification does provide a definition but the definition is not exclusive such that all other meanings of "active AT3" are not applicable. Therefore, all proper meanings have been considered and the dictionary definition of "active" is reasonable.

Responding to Applicant argument that the Office has not established that concentrated ATIII has inherent antiangiogenic or antiarteriogenic properties or set forth a *prima facie* case of anticipation, the claimed effects do not make the instant claims patentable over the prior art because the antiangiogenic and antiartiogenic effects of AT3 are inherent properties of the compound.

> MPEP 2112.02: PROCESS CLAIMS - PRIOR ART DEVICE ANTICIPATES A CLAIMED PROCESS IF THE DEVICE CARRIES OUT THE PROCESS DURING
>
> Under the principles of inherency, if a prior art device, in its normal and usual operation, would necessarily perform the method claimed, then the method claimed will be considered to be anticipated by the prior art device. When the prior art device is the same as a device described in the specification for carrying out the claimed method, it can be assumed the device will inherently perform the claimed process. In re King, 801 F.2d 1324, 231USPQ 136 (Fed. Cir. 1986) See also In re Best, 562F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977) Ex parte Novitski, 26 USPQ2d 1389 (Bd. Pat. App. & Inter. 1993

Thus, the disclosure meets the claims because ATIII is administered to patients for the treatment of infectious vasculitis and rheumatoid arthritis. The mechanism by which the ATIII achieves a

therapeutic effect is an inherent feature of the process. Furthermore, there is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. Schering Corp. v. Geneva Pharm. Inc., 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003).

Romisch also meets the limitations of new claims 17-19. Romisch teaches the use of a purified concentrate (col. 3, line 36). A purified concentrate naturally consists of the active alpha and beta isoforms and lacks the latent form since the latent form must be produced by a laboratory method. Romisch does not disclose a special procedure to make the latent AT3. Furthermore, the AT3 used by Romisch is intact or uncleaved because he states that the AT# used in Ex. 2 was catalytically active and that complexing AT3 with other factors limited proteolytic cleavage of AT3, thereby enhancing its activity (col. 18, lines 1-15).

Claims 8-16 stand rejected under 35 U.S.C. 102(e) as anticipated by Green et al. (US 6,593,291) in light of **Webster's Dictionary** (1994).

Applicant argues that the Office's interpretation of "active" does not take into account the definition for "active antithrombin III" which is provided in the instant specification. Applicant asserts that Green does not anticipate the instant claims because one of ordinary skill in the art could not "at once envisage" the active ATIII recited in claim 8 an dependent claims thereof regarding the type of isoforms. Applicant argues that Green discloses a vast number of proteins that binds or affects the activity of tissue factor but not any particular mixtures or isoforms or active, wherein active means "intact" ATIII. Applicant states that Green uses a cleaved form or ATIII.

Responding to Applicant's argument that the interpretation of "active" in the instant rejection does not take into account the definition for active ATIII in the specification, it is noted in the MPEP that the claims should be given their broadest, reasonable interpretation. All reasonable definitions are considered unless the text of the specification makes it clear that a word had a special meaning, see the

MPEP 2105 *supra*. In the instant case, the specification does provide a definition but the definition is not exclusive such that all other meanings of "active ATIII" are not applicable. Therefore, all proper meanings have been considered and interpretation of the phrase "active AT3" to mean that that the AT3 is capable of functioning as an anti-angiogenic agent is reasonable. In light of this interpretation, Green et al. disclose methods of controlling undesirable cell proliferation related to angiogenesis comprising the administration of AT3 to a human or animal in need thereof. Responding to Applicant's argument regarding Green's disclosure of "a vast number of proteins," this is considered irrelevant because the disclosure of other types of proteins in the disclosure of Green does not alter the fact that Green teaches controlling undesirable cell proliferation related to angiogenesis by the administration of AT3. Regarding Applicant's argument that Green does not teach the compositions of newly added claims 17-19, these claims are not included in the instant rejection.

Claims 8-10, 13 and 15 stand rejected under 35 U.S.C. 102(b) as anticipated by Emerson (Blood Coag. Fibrinol. (1994) 5(1): S37).

Applicant argues that the Office's interpretation of "active" does not take into account the definition for "active antithrombin III" which is provided in the instant specification and that Emerson does not teach if the ATIII used was intact or if a particular isoforms had been used. Applicant further argues that ATIII is known to have a number of actions but the use of ATIII as an anti-inflammatory agent does not necessarily means that the same administration of ATIII will inhibit angiogenesis or arteriogenesis.

Responding to Applicant's argument that the interpretation of "active" in the instant rejection does not take into account the definition for active ATIII in the specification, it is noted in the MPEP that the claims should be given their broadest, reasonable interpretation. All reasonable definitions are considered unless the text of the specification makes it clear that a word had a special meaning, see the MPEP 2105 *supra*. In the instant case, the specification does provide a definition but the definition is not

exclusive such that all other meanings of "active ATIII" are not applicable. Therefore, all proper meanings have been considered and interpretation of the phrase "active AT3" to mean that that the AT3 is capable of functioning as an anti-angiogenic agent is reasonable. In light of this interpretation, Emerson's teaching of treating mammals having an infection with ATIII meets the claims since the disclosed steps are the same as the claimed steps and the administration of ATIII to the mammals for the claimed purpose.

The claimed effects do not make the instant claims patentable over the prior art because the anti-angiogenic and anti-artiogenic effects of ATIII are inherent properties of the compound see MPEP 2112.02 *supra*. The mechanism by which the ATIII achieves a therapeutic effect is an inherent feature of the process. Furthermore, there is no requirement that a person of ordinary skill in the art would have recognized the inherent disclosure at the time of invention, but only that the subject matter is in fact inherent in the prior art reference. Schering Corp. v. Geneva Pharm. Inc., 339 F.3d 1373, 1377, 67 USPQ2d 1664, 1668 (Fed. Cir. 2003).

Regarding Applicant's argument that Emerson does not teach the compositions of newly added claims 17-19, these claims are not included in the instant rejection.

Claim Rejections - 35 USC § 103

Claims 8, 10 and 16 stand rejected under 35 U.S.C. 103(a) as being unpatentable over in view of O'Reilly (US 2002/0076413) in view of Antunes et al. (Int. J. Leprosy (June 2000) 68(2): 143) and **Webster's Dictionary** (1994).

Applicant argues that the requirements for a prima facie case of obviousness have not been met because O'Reilly does not suggest using "active AT3" as defined by the instant specification and that O'Reilly does not teach the alpha or beta isoforms. Applicant further argues that there is no motivation to combine the references and that there is no reasonable expectation of success because O'Reilly teaches away from the use of the "S-AT3" form for combating angiogenesis. Applicant asserts that Antunes et al. does not cure these deficiencies because it does not discuss AT3.

Responding to Applicant's argument that there is no prima facie case because O'Reilly teaches away from using active AT3 as defined in the instant specification, it is noted in the MPEP that the claims should be given their broadest, reasonable interpretation: All reasonable definitions are considered unless the text of the specification makes it clear that a word had a special meaning, see the MPEP 2105 *supra*. In the instant case, the specification does provide a definition but the definition is not exclusive such that all other meanings of "active AT3" are not applicable. Therefore, all proper meanings have been considered and the dictionary definition of "active" is reasonable. Claim 8 is drawn to treating disorders characterized by angiogenesis or arteriogenesis and the specification shows that AT3 has anti-angiogenic activity. Thus, the phrase "active AT3" is interpreted to mean that that the AT3 is capable of functioning as an anti-angiogenic agent. In light of this interpretation, O'Reilly anticipates the claims because he teaches isoforms of AT3, i.e. R-AT3, that have anti-angiogenic activity for treating the claimed diseases. Therefore, the disclosure by O'Reilly does not teach away from the use of active AT3 to treat diseases relation to angiogenesis or arteriogenesis.

Regarding Applicant's argument that O'Reilly does not teach the compositions of newly added claims 17-19, these claims are not included in the instant rejection.

Antunes was relied upon to demonstrate the relationship between angiogenesis in the cutaneous lesions of leprosy which provided motivation to employ AT3 to treat leprosy since O'Reilly have demonstrated that AT3 is effective for treating diseases related to angiogenesis.

Claims 8, 10 and 16 stand rejected under 35 U.S.C. 103(a) as being unpatentable over in view of Green et al. (US 6,593,291) in view of Antunes et al. (Int. J. Leprosy (June 2000) 68(2): 143) and **Webster's Dictionary** (1994).

Applicant argues that the rejection is traversed for the same reasons discussed in the rejection over the combination with O'Reilly.

Responding to Applicant's argument that there is no prima facie case because Green does not teach the use of active AT3 as defined in the instant specification, it is noted in the MPEP that the claims should be given their broadest, reasonable interpretation. All reasonable definitions are considered unless the text of the specification makes it clear that a word had a special meaning, see the MPEP 2105 *supra*. In the instant case, the specification does provide a definition but the definition is not exclusive such that all other meanings of "active AT3" are not applicable. Therefore, all proper meanings have been considered and interpretation of the phrase "active AT3" to mean that that the AT3 is capable of functioning as an anti-angiogenic agent is reasonable. In light of this interpretation, Green et al. disclose methods of controlling undesirable cell proliferation related to angiogenesis comprising the administration of AT3 to a human or animal in need thereof. Therefore, the disclosure by Green does not teach away from the use of active AT3 to treat diseases relation to angiogenesis or arteriogenesis.

Regarding Applicant's argument that Green does not teach the compositions of newly added claims 17-19, these claims are not included in the instant rejection.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing

date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Hanley whose telephone number is 571-272-2508. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Susan Hanley
Patent Examiner
1651

JEAN C. WITZ
PRIMARY EXAMINER